K061905
p1/2

Chapter 2 – 510(k) Summary

NOV - 8 2006

Chapter 2 contains summary information, which is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter

Medcon, a McKesson Company
3 Tevuot Ha'aretz Street
Tel Aviv 69546
Israel
Tel: +972 3 648 7702
Fax: +972 3 647 8593

Predicate Device(s)

Horizon Cardiology ECG is substantially equivalent to a combination of the following predicate devices:

- Pyramis™ ECG Management system (K032038)
- Ascentia HeartStation™ (K050858)
- Infinity MegaCare™, manufactured by Siemens Medical Solutions (K031970)

Name of the Device

Horizon Cardiology ECG™ (HC ECG™ for brevity)

Description of the Device

HC ECG™ is a comprehensive ECG management system for importing ECG waveform data, reviewing and performing measurements, diagnosis and comparison of ECG procedures and storing the data for future review and management.

HC ECG™ functions as a non-real time system. It receives ECG procedure files after the cessation of the ECG procedure, which can originate from any one of a variety of manufacturer's cardiographs. HC ECG™ acquires the ECG waveforms through a network connection or via a diskette, and normalizes them to a common format. If the ECG cart has made an ECG procedure analysis, HC ECG™ presents it and utilizes the Glasgow University Interpretive Algorithm to perform its own measurements, diagnosis and serial comparison without changing the raw waveform data.

The HC ECG™ graphic user interface provides tools that enable the physician to:

- edit measurements.
- edit procedure diagnoses.
- review numerous ECG procedures concurrently.
- confirm ECG procedures.
- distribute and print ECG procedure reports.

HC ECG™ complies with HL7 standards for export of reports to the Hospital Information System. HC ECG™ supports final ECG report distribution by printing, faxing, e-mailing and automatic export to other systems. The Horizon Cardiology ECG™ database complies with the requirements of HIPAA through robust password security, record access security and file allocation in a secure and managed server.

Horizon Cardiology ECG ™ allows access to ECG records from web-enabled PCs throughout a network and enables authorized clinical users to access the system from remote locations.

Intended Use

HC ECG™ is a software application designed for use in various hospital departments, to import, display, store, analyze, distribute and process ECG procedures from resting ECG devices.

The HC ECG™ is intended to provide analysis or reanalysis of resting ECG's and to provide preliminary data for editing and confirmation by an over-reading physician. The HC ECG™ may provide a serial comparison of ECG data to facilitate the review of the patient's current ECG with previous ECG's of the same patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medcon Ltd.
c/o Jonathan S. Kahan
Partner
Hogan & Hartson L.L.P.
555 13th Street
Washington D.C. 20004

NOV - 8 2006

Re. K061905
Trade Name: Horizon Cardiology ECG
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II
Product Code: DQK
Dated: October 10, 2006
Received: October 11, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061905

Device Name: Horizon Cardiology ECG™

Indications for Use:

Horizon Cardiology ECG™ is a system for importing, storing, displaying and reviewing ECG procedures. Horizon Cardiology ECG is intended for use in the hospital environment by medical professionals.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061905